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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,296

08/06/2002

Maurice Israel

033525-002

9468

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01/05/2005

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/049,296

**Applicant(s)**

ISRAEL ET AL.

**Examiner**

Christopher J Nichols, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-45 is/are pending in the application.
- 4a) Of the above claim(s) 27-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-26 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☒ Claim(s) 17-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2.11.02</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 17-26) in the reply filed on 25 October 2004 is acknowledged. The traversal is on the ground(s) that Groups I and II share the same special technical feature and their searches are co-extensive. This is not found persuasive because Group I is drawn to a method of making calibrated mammalian microcubes of cerebral material while Group II is drawn to a screening method. Neither Group shares the same technical feature. Also, each group pertains to a separate and distinct field of search, thus imposing an undue search burden on the Examiner. Claims **27-45** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 25 October 2004. The requirement is still deemed proper and is therefore made FINAL.

### ***Status of Application, Amendments, and/or Claims***

2. The Preliminary Amendment filed 11 February 2002 has been received and entered in full.
3. The Preliminary Amendment filed 6 August 2002 has been received and entered in full.

### ***Specification***

4. The Abstract is objected to because of the use of legal phraseology. Applicant is reminded of the proper language and format for an abstract of the disclosure.

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5. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
6. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.
7. The disclosure is objected to because of the following informalities: not art-accepted of abbreviation "gaba" should be capitalized "GABA" (throughout Specification). Appropriate correction is required.

#### ***Claim Objections***

8. Claim 20 is objected to because of the following informalities: claim 20 uses "in" instead of the accepted "of" preposition for the transition phrase "consisting" (i.e. "consisting of"). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 17 uses the phrase “mammal Krebs solution” when the art accepted term is “Krebs solution”. Thus it is not clear what the metes and bounds of this phrase are, particularly if “mammal Krebs solution” is chemically different from the art accepted “Krebs solution” and “Krebs Ringer Solution”.

11. Claim 17 uses the term “appropriate”. Neither the Specification nor the prior art teaches the metes and bounds for what constitutes an “appropriate mesh diameter”.

12. Claim 26 uses the term “appropriate”. Neither the Specification nor the prior art teaches the metes and bounds for what constitutes an “appropriate volume”.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 17-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Reddy & Sastry (25 May 1979) “Studies on neurotransmitter-stimulated phospholipid metabolism with cerebral tissue suspensions: a possible biochemical correlate of synaptogenesis in normal and undernourished rats.” Brain Research 168(2): 287-298.

14. Reddy & Sastry teach a method of isolating a preparation of rat cerebral tissue comprising mincing said tissue in Krebs-Ringer solution, then passing said tissue in Krebs-

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Ringer solution through a nylon bolting cloth, and harvesting the resulting tissue thus meeting the limitations of claim 17, 20, and 21 (pp. 289). The tissue is minced in a small volume of 1ml/g tissue roughly equivalent to the claimed volume of 1 to 2 mm<sup>3</sup> thus meeting the limitations of claim 17.

15. The rat cerebral samples consisted of “whole brain” preparations defined by Reddy & Sastry as “cortex, cerebellum, and brain stem” thus meeting the limitations of claims 18 and 20 (pp. 288-289). Reddy & Sastry also teaches the dissection of the brain preparations into three anatomical regions, the cortex, cerebellum, and brain stem thus meeting the limitations of claim 19 (pp. 289).

16. Reddy & Sastry teaches that the nylon bolting cloth used had mesh sizes of 44, 130, 264, 433  $\mu$ m which correspond to 0.044, 0.130, 0.264, and 0.433 mm mesh sizes thus falling into the range of 0.01 and 2 mm<sup>2</sup> thus meeting the limitations of claim 22 (pp. 289).

17. Reddy & Sastry teaches that the tissue preparation was left in a 25 mL conical tube, due to the force of gravity the cubed tissue would fall to the bottom of the tube being equivalent to “spontaneous sedimentation” thus meeting the limitations of claim 23 (pp. 289).

18. Reddy & Sastry also teach the brain preparation itself (the isolation thereof as described) above thus meeting the limitations of claims 24 and 26 (pp. 288-289).

19. Since the nylon bolting cloth taught by Reddy & Sastry teaches had mesh sizes of corresponding to 0.130, 0.264, and 0.433 mm mesh sizes thus falling into the range of 0.1 and 5 mm<sup>3</sup> (the cubed tissue which results from being passed through the mesh) thus meeting the limitations of claim 25 (pp. 289).

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20. Claims 17, 18, 20, 21, 24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Helme-Guizon *et al.* (July 1998) "Increase in syntaxin 1B and glutamate release in mossy fibre terminals following induction of LTP in the dentate gyrus: a candidate molecular mechanism underlying transsynaptic plasticity." Eur J Neurosci. 10(7): 2231-7 (IDS).

21. Helme-Guizon *et al.* teaches a method of isolating the CA region of rat hippocampus comprising dissecting out the brain tissue to an approximate volume of 1 mL, roughly equivalent to 1 mm<sup>3</sup>, diluting in 2 mL Krebs solution, roughly equivalent to 2 mm<sup>3</sup> and then passing said cells through a nylon gauze thus meeting the limitations of claims 17, 20, 21, 22, 23 (pp. 2233). The nylon mesh used has a mesh size of 50 µm which is equivalent to 0.05 mm<sup>3</sup> thus meeting the limitations of claim 22 (see metric table included). The filtrate is allowed to sediment and then collected thus meeting the limitations of claims 23-26 (pp. 2233).

22. Claims 24, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Garthwaite *et al.* (1980) "A Morphological Study of Incubated Slices of Rat Cerebellum in Relation to Postnatal Age." Dev. Neurosci. 3(2): 90-99.

23. Garthwaite *et al.* teaches a preparation of rat cerebella in Krebs solution which the approximate dimensions of 0.4 X 0.4 mm, the slices already having a third dimension of approximately 0.38 mm from dissection thus meeting the limitations of claims 24-26 (pp. 91).

24. While the cerebellum preparation described by Garthwaite *et al.* was not "obtained by the method of claim 17", it has been established by the courts that a product inherently possesses characteristics of that product (i.e. including the amino acid sequence of a protein). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

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“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved”. *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

25. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*., 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

### *Summary*

26. No claims are allowed.



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***Conclusion***

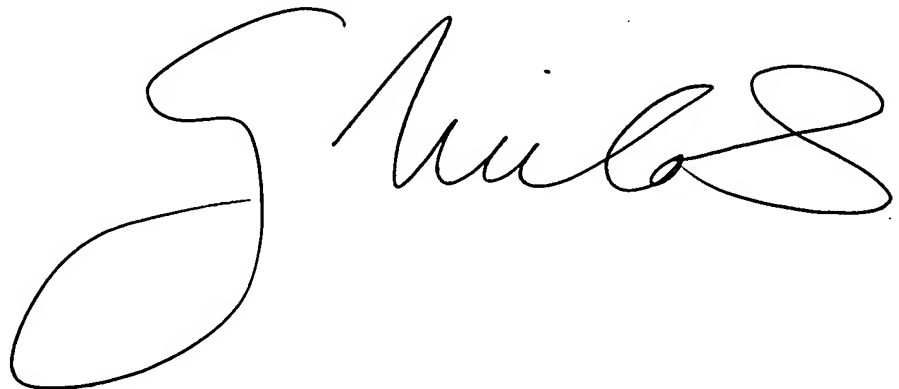
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

January 3, 2005

A large, stylized handwritten signature in black ink, appearing to read "Nichols". The signature is written in a cursive style with a large loop at the beginning and a long, sweeping tail.